

STATEMENT OF WORK (SOW)
For The
Biological Threat Reduction Program (BTRP) Implementation in Azerbaijan

1 BACKGROUND

The U.S. Department of Defense (DoD) partners with the Government of Azerbaijan through DoD's Cooperative Threat Reduction (CTR) Biological Threat Reduction Program (BTRP). The CTR BTRP aims to counter the threat of bioterrorism and prevent proliferation of biological weapons technology, pathogens and expertise at the source in Azerbaijan. DoD will assist Azerbaijan as a partner in the successful global elimination of biological weapons and the prevention of bioterrorism through implementing DoD's three integrated CTR BTRP project areas:

- 1) **Biosecurity and Biosafety (BS&S):** Provides biosecurity and biosafety upgrades at institutes engaged in public health research on dangerous pathogens to prevent the proliferation of biological weapons (BW) materials and technologies to terrorists or rogue states and to ensure the safe and secure storage and handling of dangerous biological pathogens used for peaceful research at pathogen repositories and in laboratories to prevent accidental release, theft, and exposure.
- 2) **Biological Threat Agent Detection and Response (TADR):** Promotes biosecurity and biosafety at biological facilities in Azerbaijan by strengthening dangerous pathogen detection and response networks, enhances Azerbaijan's ability to detect and respond to infectious disease outbreaks, whether they be natural outbreaks that could be exploited by bioterrorists or outbreaks caused by bioterrorists, and assists in consolidating dangerous pathogen collections in a safe, secure central diagnostic reference laboratory.
- 3) **Cooperative Biological Research (CBR):** Engages former BW scientists in research that supports peaceful pursuits in order to prevent the proliferation of BW expertise to terrorist groups and rogue states.

This project will be executed pursuant to the Biological Threat Reduction Implementing Agreement (BTRIA) signed by DoD and the Cabinet of Ministers (CoM) on 6 June 2005 as amended and extended.

The BTRP consists of several components:

Biological Security ("Biosecurity"): The end state will be an integrated security system designed and installed at engaged sites, operated by the recipient state government, that detects, assesses, delays, responds to, and recovers from any attempt to steal, divert, or remove EDP from the facility. The aim is to engage and then defeat the threat. The Azerbaijan government provides guard force; the U.S. Government provides equipment and training. Security is commensurate with the volume and types of EDP on hand.

Biological Safety ("Biosafety"): The end state will be laboratories at engaged sites that provide a safe facility in which the laboratory personnel can work with Especially Dangerous Pathogens (EDP) and that preclude the accidental release of agents into the outside environment. The

standards for biosafety will be those of the United States (specifically U.S. Health and Human Services Publication No. (CDC) 93-8395 *Biosafety in Microbiological and Biomedical Laboratories* current edition (the BMBL)), tempered by Azerbaijani laws and regulations.

Central Reference Laboratory (CRL)—human, veterinary, or combined facility—A fully equipped laboratory capable of confirming the diagnosis of diseases by definitive identification of the pathogens of concern. The CRL has biosafety level (BSL) 1, 2, and 3 capabilities in its research space as well as full operating capabilities for projects in each recipient state. The CRL is the top-level (i.e., federal-level) laboratory used in the TADR network inside Azerbaijan

Electronic Integrated Disease Surveillance System (EIDSS)—A computerized disease surveillance system to monitor and track human and veterinary data on EDP, which is a key role of the TADR network inside each country. Linkages will exist throughout each country and deposit veterinary and human health data at the Central Data Repositories at the CRL. Data also will be available to U.S. Government recipients in near-real-time.

Epidemiological Monitoring Station (EMS)—human, veterinary, or combined facility—Typically a renovated laboratory at an existing zonal/regional Ministry of Health (MOH), Ministry of Agriculture (MOA), and Ministry of Defense (MOD) facility that performs mid-level tests and diagnoses for the TADR network inside Azerbaijan and operates at BSL2. Each EMS is upgraded with a computer and other equipment for electronic disease reporting and surveillance using EIDSS. The EMS also receives equipment for the safe collection, handling, temporary storage, and transport of clinical samples and diagnostic capabilities for the EDP identified as of interest by the BTRP.

Zonal Sentinel Station (ZSS)—veterinary—A renovated laboratory converted from an existing zonal/regional MOA facility that performs basic tests for the TADR network in Azerbaijan. Each ZSS is upgraded during conversion with a computer and other equipment for electronic disease reporting and surveillance using EIDSS. The ZSS also receives equipment for the safe collection, handling, temporary storage, and transport of clinical samples.

Mobile Outbreak Response Unit (MORU)—An integrated unit consisting of an interdisciplinary team of epidemiologists, laboratorians, physicians, and/or veterinarians deployed from the republican level to provide additional capacity and/or expertise for the TADR network whenever regional/zonal resources are not sufficient to control an outbreak. Also included in the MORU is equipment, vehicles, and supplies, which will flow from the local EMS and be upgraded by native response as appropriate.

Pathogen Asset Control System (PACS)—A secure, stand-alone, computerized inventory and repository system for collections of EDP.

Threat Agent Detection and Response (TADR)—The TADR network has the following objectives: strengthen the capability of existing human and veterinary infectious disease surveillance networks by improving diagnostic laboratories; create republic-level CRL that uses state-of-the-art diagnostic capabilities and modern communications and feature an information

technology backbone; deploy mobile response teams to permit rapid, effective response to potential threat agent incidents; consolidate all EDP collections and research to the CRL; and transfer newly acquired pathogen strains to U.S. Government-accessible laboratories for prophylactic, protective, and other peaceful purposes.

Cooperative Biological Research (CBR) - Engages former biological weapons (BW) scientists in research that supports peaceful pursuits in order to prevent the proliferation of BW expertise to terrorist groups and rogue states.

2 TASK ORDER OBJECTIVES

The purpose of this task order is to integrate all BTRP projects in Azerbaijan including current projects, and projects to be established and completed under this task order. The contractor shall upgrade five (5) human and four (4) veterinary laboratories to EMSs and eight (8) veterinary facilities to ZSSs, conduct and coordinate BTRP training, and support and administer research projects. The training and logistics support will be a parallel effort to support the upgrades and will commence with technical direction of DTRA. The contractor shall perform the work as outlined in the following paragraphs.

System Design and Strategic Planning

- 2.1 Using a systems engineering approach, develop an Integrated Implementation Master Plan (IIMP). The IIMP shall demonstrate the overall approach and execution plan for BTRP implementation in Azerbaijan, including but not limited to: system operations and interoperability, quality assurance and quality control plan, training, testing and evaluation plans, sustainment, and system turnover. (CDRL A007)
- 2.2 Develop an Integrated Implementation Master Schedule (IIMS). This shall include all activities outlined in this contract as well as activities carried out by USG entities (i.e., WRAIR, USAMRIID, CDC, etc.) (CDRL A008)

Epidemiological Monitoring Station (EMS)

- 2.3 With DTRA technical direction, the contractor shall conduct site analyses at Centers for Hygiene and Epidemiology (CH&Es) and Anti-Plague Stations (APS) sites in designated rayons to evaluate suitability as an EMS and report upon current site conditions, staff capability, and security systems. Provide analysis, recommendations, and conceptual design to DTRA (CDRL A009). BTRP designated rayons for EMS locations are as follows:

- 2.3.1
- 2.3.2
- 2.3.3
- 2.3.4
- 2.3.5
- 2.3.6

(b)(2)

- 2.3.7 (b)(2)
- 2.3.8
- 2.3.9

- 2.4 Upon approval of the conceptual design by DoD, complete a detailed site design (CDRL A011) for each of the sites showing the details of the improvements. The designs shall incorporate approved BTRP equipment.
- 2.5 Renovate and/or construct, commission, and install and certify equipment into state-of-the-art BSL-2 diagnostic labs. (CDRL A011) EMSs shall be part of the BTRP TADR network and shall serve as a regional resource for diagnostics in the area. In addition, EMSs shall be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism emergency.

Zonal Sentinel Sites (ZSS)

- 2.6 With DTRA technical direction, the contractor shall conduct site analyses at veterinary laboratory sites in designated rayons to evaluate suitability as a ZSS and report upon current site conditions, staff capability, and security systems. Provide analysis, recommendations, and conceptual design to DTRA (CDRL A009). BTRP designated rayons for ZSS locations are as follows:

- 2.6.1 (b)(2)
- 2.6.2
- 2.6.3
- 2.6.4
- 2.6.5
- 2.6.6
- 2.6.7
- 2.6.8

- 2.7 Upon approval of the conceptual design by DoD, complete a detailed site design for each of the sites showing the details of the improvements. The designs shall incorporate only approved BTRP equipment.
- 2.8 Renovate, commission, and install and certify equipment into limited BSL-2 diagnostic labs. (CDRL A011) ZSSs shall be part of the BTRP TADR network and shall serve as a regional resource for limited diagnostics in the area. In addition, ZSSs shall be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism emergency.

Biosafety and Biosecurity

2.9 Meet and maintain U.S. standards for biosafety and DoD standards for biosecurity (excluding the requirement for polygraph testing) necessary for diagnostics of BTRP Priority Pathogens at all BTRP facilities.

2.10 Ensure that there are U.S. standard laboratory biosafety practices in place, including a system for reporting exposures to pathogens; self aid and first aid capabilities; and personnel reliability systems at all BTRP facilities

Cooperative Biological Research

2.11 Coordinate and assist DoD scientific collaborators in the development of research proposals. Conduct administrative management of projects from conception through closeout. Establish and distribute grant payments. Procure equipment necessary to complete projects at each site. Maximize use of the BTRP renovated facilities to the extent possible.

Equipment Procurement

2.12 Procure equipment necessary to complete full installation at each site. See Attachment 1. Ensure compliance with DTRA shipping and export procedures. (CDRL A013)

Installation

2.13 Upon review and approval of the design by DoD, install the equipment according to the site design packages; perform the necessary operational tests; turn over the equipment to MoH, MoA or MoD and provide As-Built documentation and certificate of completion (CDRL A011).

System Operations

2.14 Ensure that data generated through BTRP laboratory network are comparable and reliable, and can also be compared to data generated in other DoD and USG- funded projects. Considerations include: standard protocol for diagnostic tests, quality assurance and quality control, system readiness for periodic auditing by an external tester, reliable supplier(s) of and sustained access to all test reagents; and use of BTRP standardized equipment and reagents.

Sustainment

2.15 **Maintenance and Warranty.** Provide maintenance and warranty coverage for as necessary to sustain the program through the period of performance. The contractor shall advise DTRA if certain elements will require extended warranty coverage. The coverage will also include recommended periodic maintenance activities for the equipment and the provision for spare parts. Provide this information in the form of a plan for continued maintenance adequate to provide to the Government of Azerbaijan (CDRL A007).

2.16 Warehousing and Distribution. Use existing Government of Azerbaijan supply and distribution systems. Provide technical expertise and advice to ensure that the existing supply network can support BTRP implementation. Where existing networks are not capable of supporting the BTRP, the contractor shall focus on enhancing those networks needed capabilities. In order to achieve the ultimate goal of the Government of Azerbaijan maintaining a self-sufficient warehousing and distribution network capable of supporting BTRP, the contractor shall:

- ensure that an established distribution network effectively re-supplies BTRP facilities in a timely fashion;
- involve existing Azerbaijani procurement assets in strategy and source selection of material for the BTRP system. The ultimate goal being that internal Azerbaijani procurement structures can independently support the TADR network. Consumable material sourcing will be based on cost, schedule, and performance of vendors, and an emphasis on local sourcing;
- take special handling requirements and the perishable nature of material into account when packing, handling, storing and transporting stock to laboratory sites;
- ensure that the design of the Azerbaijani warehouses allow for the greatest possible efficiencies in operation while maintaining recognized safety standards and norms;
- provide for adequate temperature controlled storage and transport of material from the warehouse to laboratory sites;
- develop a set of standard operating procedures that enforces warehouse processing efficiencies;
- ensure that Azerbaijani warehouse personnel are fully trained and certified in international packing and handling norms;
- develop an inventory system that has the capability to track consumable needs and trends among BTRP sites in cooperation with the existing Azerbaijani supply networks; and
- base their sourcing of consumables upon the cost, schedule and performance of vendors and shall place an emphasis on local sourcing of material.

Training and Coordination

2.17 Develop and execute a training program for the newly installed equipment for Azerbaijani personnel at the operator, maintainer and system administrator levels. Provide lesson plans and training aids as required.

2.18 Integrate and coordinate all BTRP training activities associated with the BTRP effort in Azerbaijan. Activities include soliciting proper training participants, reserving a venue, distributing letters of invitation, issuing training certificates, communicating training plan to institute-level directors and participants, verifying to trainer and DTRO-B that all training needs or requirements (materials, equipment, supplies) are available in advance of the training, and providing administrative assistance for the execution of all BTRP workshops and training activities to include preparation of minutes and summaries. Conduct subject matter expert training with technical direction by DTRA to fill gaps in

BTRP training program. Submit a BTRP Training Master Plan as part of the IIMP. (CDRL A007). A representative list of training modules is included at Attachment 2.

- 2.19 Establish and maintain a database of records for training conducted in support of BTRP in Azerbaijan. This database shall include electronic copies of course modules and training materials, attendance rosters, training report (CDRL A012).
- 2.20 Provide all training materials to DTRO-B, TRSC, and government of Azerbaijan officials for review and accreditation with technical directed from DTRA.

Central Reference Laboratory

- 2.21 Procure, deliver, install and certify equipment into an existing renovated facility to provide a comprehensive, state-of-the-art BSL-3 biocontainment laboratory space and the associated BSL-2 laboratory space, animal facilities, clinical facilities and research support space. The CRL will serve as a national resource for efforts in conducting clinical and laboratory research and testing on hazardous biological agents in support of the BTRP Research Agenda. The CRL must preferentially support the DoD funded research activities, as well as other USG funded research. In addition, the CRL must be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism emergency.
- 2.22 Site adapt the existing 4-Story Prototype CRL design to support construction and commissioning of a new, state-of-the-art BSL-3 biocontainment laboratory with associated BSL-2 laboratory space, animal facilities, clinical, research, training, administration and ancillary support spaces and systems.
- 2.23 Develop and install the Biosecurity system at the CRL. Conduct Vulnerability Assessment (VA) of current biosecurity system and procedures in place at CRL location. Perform gap analysis using DTRA approved modeling system and provide an analysis of alternatives for the installation of a biosecurity system to DTRA. Upon selection of option by DTRA, perform related security system upgrades, equipment procurement and installation, and training.

In addition to the above, the task order will include an option for additional work on the Central Reference Laboratory (CRL). This option is in the current scope of T.O. 112.

- 2.24 **Option 1 -** Provide construction management and oversight of a Government of Azerbaijan renovation and/or construction and commissioning of a state-of-the-art BSL-3 biocontainment laboratory space and associated BSL-2 laboratory space, animal facilities, clinical facilities and research support space.

3 GENERAL REQUIREMENTS

- 3.1 **Contractor/Task Order Manager Communication.** The contractor shall meet with the Government within 10 days of task order award. During the first month of the contract,

the contractor shall meet weekly with the Task Order Manager (COR). This can be accomplished via telephone conference if agreed to by the DTRA. Program Management Review meetings will be held quarterly in a location as determined by DTRA. The contractor shall prepare written minutes of meetings (CDRL A014) and submit them to the DTRA for approval. The minutes shall be signed by the contractor, the CO and the DTRA.

- 3.2 **Safety.** The contractor is responsible for developing and implementing a Safety Analysis and Management Plan and passing the requirements through to all sub-contractors employed on the project.
- 3.3 **Quality Assurance.** The Defense Contract Management Agency (DCMA) will function as the government's oversight for quality assurance and payments for equipment purchased.
- 3.4 **Contracting Officer Representative (COR).** The COR is a representative of the CO and will participate in the administration of this contract except where stated. After contract award the name and phone number of the COR will be furnished to the contractor.
- 3.5 **Discrepancies.** The COR will notify the contractor's project manager when discrepancies occur and the COR will request corrective action. The COR will make written records of discrepancies and will ask the contractor's project manager (or authorized representative) to acknowledge the discrepancy by initialing the record.
- 3.6 **Scope Changes.** Any matter concerning a change in scope, price, terms or conditions of this contract shall be referred to the CO.
- 3.7 **Logistics.** The contractor is responsible for coordinating shipment of equipment to BTRP locations. The contractor shall ship all equipment as identified. The Contractor shall comply with all CTR Program requirements for marking, packaging, and documentation (base contract CDRLs A002 and A004).
- 3.8 **Equipment Accountability.** The contractor shall provide Master Inventory and Property Lists of all Contractor Acquired Property, as specified in the base contract (base contract CDRLs A001 and A003).
- 3.9 **Project Manager.** The contractor shall identify the responsible person with the authority to make decisions on all contract matters and include the name and resume in the Top-Level Work Plan. He/she shall be able to read, write and speak English.

REPORTS

3.10 Cost Performance Report: Sixty days after contract award, and monthly thereafter, submit a Cost Performance Report. (base contract CDRL A005).

3.11 Closeout and Turnover Report. The contractor is responsible for compiling all the necessary documentation for contract closeout and turnover. The contractor shall request a

meeting with the COR 90 days prior to closeout, the contractor will coordinate with the COR to ensure all required documentation is completed and closeout occurs in a timely manner. (base contract CDRL A006)

4 DELIVERABLES

The following are deliverables during the course of the contract:

CDRL#	Description of Deliverable
A001 (base)	Master Inventory List
A002 (base)	Special Shipping Handling and Transportation Planning Documents
A003 (base)	Master Property List
A004 (base)	Packaging, Marking and Documentation
A005 (base)	Cost Performance Report
A006 (base)	Transfer of Custody
A007	Integrated Implementation Master Plan
A008	Integrated Implementation Master Schedule
A009	Conceptual Design and Site Analyses
A010	Intentionally Not Used
A011	EMS/ZSS Certificate of Completion and As-Built Drawings
A012	Comprehensive Set of Training Materials / Training Database
A013	Data Accession List (DAL)
A014	Quarterly Program Management Review Meeting Minutes

5 APPLICABLE DOCUMENTS

- 5.1 Agreement Between the Government of the United States of America and the Government of the Republic of Azerbaijan Concerning Cooperation in the Area of Counter Proliferation of Weapons of Mass Destruction and Defense Activities, dated September 28, 1999. (US-Azerbaijan CTR Umbrella Agreement)
- 5.2 Agreement Between the Department of Defense (DoD) of the United States of America and the Cabinet of Ministers of the Republic of Azerbaijan Concerning Cooperation in the Area of Prevention of Proliferation of Technology, Pathogens, and Expertise that Could be Used in the Development of Biological Weapons, dated June 6, 2005. (Biological Threat Reduction Implementing Agreement).
- 5.3 Presidential Decree, dated August 3, 2005, Confirming the Agreement Between the Department of Defense and the Cabinet of Ministers of Azerbaijan on Cooperation in Prevention of Proliferation of Technology, Pathogens, and Expertise that Could be Used in the Development of Biological Weapons, dated June 6, 2005.